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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/331,127	10/19/1999	DONALD G. MUNROE	016777-0344	1284

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

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11/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/331,127	MUNROE ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-24 and 26-43* is/are pending in the application.

4a) Of the above claim(s) *36* is/are withdrawn from consideration.

5)☒ Claim(s) *20-24,26,27,32-35,37-40 and 43* is/are allowed.

6)☒ Claim(s) *28-31,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Continued Examination:

1a. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 August 2007 has been entered.

Status of Claims:

1b. Claims 1-19 and 25 have been cancelled. Claims 20-24, 26-43 are pending, of which claims 20-24, 26-35 and 37-43 are under consideration. Claim 36 stands withdrawn as being drawn to nonelected invention.

Formal Matter:

2. Sequences identifiers, (SEQ ID NO) were provided for all the sequences on page 24 in the amendment filed on 20 September 2004.

3. The following previous objections and rejections are withdrawn in light of Applicants amendment filed 08/27/2007.

3a. The rejections of claims 20, 32-35, 37-38, 43 made under 35 U.S.C. 112, first paragraph for not enabling the full scope of the claimed invention and also for not complying with the written description, are withdrawn. Claims 20 has been amended to recite 95% identity with functional language, which is within the scope of the enabled

embodiments and also satisfies written description provision of 35 U.S.C. 112, first paragraph.

Claim Rejections under 35 U.S.C. §112, first paragraph:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. Claims 28-31 and 41-42 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide comprising a nucleotide sequence set forth in SEQ ID NO:11, a nucleic acid encoding the protein comprising amino acid residues 67-553, 26-553 of SEQ ID NO:12, a nucleic acid encoding a variant of the polypeptide of SEQ ID NO:12 having a substitution at position 85, wherein an arginine is substituted with a glutamine, does not reasonably provide enablement for an isolated polynucleotide which hybridizes under un specified hybridization conditions with a specific polynucleotide, wherein said polynucleotides are 90% identical or more, or an oligonucleotide comprising at least 15 nucleotides of polynucleotide encoding a specific polypeptide or a polynucleotide which is at least 80% or 90% sequence identity to a specific sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Regarding claims 28-31, the specification does not enable an isolated polynucleotide, which hybridizes under un-specified conditions to the nucleic acid encoding the polypeptides recited in claim 20, so that the hybridizing nucleic acid would

retain the functional integrity of the nucleic acid of claim 20. With respect to claims 41-42, Applicants do not disclose an isolated polynucleotide the shares at least 80% or 90% to the nucleic acid of SEQ ID NO:11, bases 320-1780 that encodes a mammalian GLP-2 receptor that binds GLP-2.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. Ex Parte Forman, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); In re Wands, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988). In the instant case, Applicants disclose a GLP2 receptor comprising amino acid residues 67-553 of SEQ ID NO:12, a second GLP2 receptor comprising amino acid residues 26-553 and a third GLP-2 receptor having a point mutation, wherein an arginine at position 85, is substituted with a glutamine, and nucleic acids encoding said receptors. However, Applicants do not disclose a polynucleotides that hybridize under unspecified conditions with the nucleic acid encoding the GLP2 receptor comprising amino acid residues 67-553 of SEQ ID NO:12, or the GLP2 receptor comprising amino acid residues 26-553, or which hybridizes to the complement of said nucleic acid, wherein said polynucleotides share 90% or more identity to said nucleic acid. Furthermore, while recombinant techniques are available, it is not routine in the art to screen large numbers of polypeptides that might potentially retain the desired activity, because the expectation of obtaining similar activity is unpredictable. Thus one of skill in the art would require

additional guidance, such as information as to what structural features of nucleic acid that would hybridize to the desired nucleic acid that would encode the desired protein. Thus, to practice the invention commensurate with the scope of the claims would result in undue experimentation.

Therefore, the instant specification is not enabling for an isolated polynucleotide which hybridizes under un specified hybridization conditions to the nucleic acid encoding the GLP2 receptor comprising amino acid residues 67-553 of SEQ ID NO:12, or the GLP2 receptor comprising amino acid residues 26-553, or hybridizes to the complement of said nucleic acid, wherein said polynucleotides share 90% or more identity to said nucleic acid, or an oligonucleotide comprising at least 15 nucleotides or of said nucleic acid, or a polynucleotide which is at least 80% or 90% sequence identity to the nucleic acid which to the nucleic acid of SEQ ID NO:11, bases 320-1780 that encodes a mammalian GLP-2 receptor that binds GLP-2.

4b. Claims 28-31 and 41-42 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record set forth in the office actions.

Applicants describe the structure of an isolated polynucleotide encoding a GLP-2 receptor comprising amino acid residues 67-553 of SEQ ID NO:12, an isolated polynucleotide encoding a GLP-2 receptor comprising amino acid residues 26-553 of SEQ ID NO:12 and an isolated polynucleotide encoding GLP-2 receptor having a point mutation, wherein an arginine at position 85, is substituted with a glutamine. However Applicants fail to describe polynucleotides, which hybridize under un-specified

conditions to the nucleic acid recited in claim 20, that would retain the functional integrity of said nucleic acid. With respect to claims 41-42, Applicants do not provide written description for an isolated polynucleotide the shares at least 80% or 90% to the nucleic acid of SEQ ID NO:11, bases 320-1780 that would encode a mammalian GLP-2 receptor that binds GLP-2.

Claim Rejections Under § 112, second paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. The rejection of claims 28-31 made under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained for reasons of record. Claims 28-31 are directed to nucleic acid molecule which "'hybridize'" or hybridize under "'high stringent conditions". Although, the specification at pages 22 and 27 discusses stringency, but a variety of conditions are indicated and it is not clear which set of conditions are to be encompassed by the claims. Furthermore, the conditions disclosed on pages 22 and 27 are not considered to be "high stringency" due to the low temperature and high salt conditions. Furthermore, with respect to claim 28, although a nucleic acid that hybridizes to the complement of the nucleic acid recited in claim 20 might encode the GLP2 receptor recited in claim 20, a nucleic acid that hybridizes to the nucleic acid encoding said GLP2 receptor would not also encode said receptor.

Response to Applicants' Amendment and Arguments:

6. Applicants argue that the specification discloses substantial written description for the amended claims, because the specification discloses a "cDNA of human origin, SEQ ID NO: 11, encodes the full length human GLP-2 receptor having residues 67-533 of SEQ ID NO: 12", and a nucleic acid encoding a human GLP-2 receptor having residues 26-533 of SEQ ID NO: 12. Applicants further argue that a third complete GLP-2 receptor chemical structure is disclosed as the point mutation corresponding to human [Glu 85]-GLP-2 receptor. Applicants contend that there is overwhelming evidence that the inventors possessed the full scope of claim 20, as amended, and of claims 28-35, 37-38, and 41-42, which depend from claim 20. With regard to claim 29, Applicants assert that claim 29 is drawn to screening probes, not coding sequences. Applicants argue that the skilled artisan would recognize that 15% of the residues are non-conservative and would also be able to determine variants with the desired activity. Applicants point to figure 9, which shows that the rat GLP-2 sequence shares 82% identity to hGLP-2 over the relevant residues. Regarding claims 28-31, Applicants argue that "high stringency" is a term of art well understood and that the specification defines the term to mean conditions that identify polynucleotides that are 90% identical or more. Applicants point to pages 22 and 27 of the specification for support for the specific hybridization condition.

These arguments have been considered but are not deemed persuasive.

Applicants are correct in that the instant specification is enabling for and provide written description for an isolated polynucleotide encoding the GLP-2 receptor comprising amino acid residues 67-553 of SEQ ID NO:12, an isolated polynucleotide

encoding the GLP-2 receptor comprising amino acid residues 26-553 of SEQ ID NO:12 and an isolated polynucleotide encoding the GLP-2 receptor having a point mutation, wherein an arginine at position 85, is substituted with a glutamine. Thus claims 20-23, 24, 26-27, 32, 33-35, 37-40 and 43 are not included in these rejections. However, the specification fails to enable the invention recited in claims 28-31 or 41-42. The specification does not disclose an isolated polynucleotide which hybridizes under the conditions cited on pages 22 and 27 that would encode the polypeptides recited in claim 20. Furthermore, the oligonucleotide recited in claims 29 and 30 would not encode the polypeptides recited in claim 20. Applicants contend that the oligonucleotide recited in claim 29 is drawn to screening probes, not coding sequences. However, claim 29 depends from claim 20, which is drawn to an isolated polynucleotide which encodes a specific polypeptide. Thus, the specification does not describe or enable an ologigonucleotide as recited in claims 29 and 30 that would encode the desired protein.

With respect to claims 41-42, the instant specification neither describes nor enables an isolated polynucleotide that is less than 100% to the nucleic acid that encodes the GLP2 receptors recited in claim 20 that would encode said receptors.

New Objections:

7a. Claims 29 and 31 are objected to, because they are improper dependent claims, since these claims refer back to claims 20 and 22.

7b. Claims 41 and 42 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s)

in proper dependent form, or rewrite the claim(s) in independent form. Claims 40 and 41 are not only broader in scope than claim 20, which they depend from, but the invention of claims 40 and 41 can be infringed without infringing the invention of claim 20.

8. ***Conclusion:***

Claims 20, 21, 22, 23, 24, 26, 27, 32, 33, 34, 35, 37, 38, 39, 40 and 43 are allowable.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday-Friday: 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art Unit 1647
07 November 2007